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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,850	05/11/2001	Kohshi Ueno	0425-0838P	7071

2292 7590 01/22/2003

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EXAMINER
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PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 01/22/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/852,850

Applicant(s)  
Kohshi Ueno et al

Examiner  
SUDHAKER PATEL, D.Sc. Tech.

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 7, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, and 6-17 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, and 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/509,778.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### DETAILED ACTION

Applicants' communication paper # 5 dated 11/7/02 is acknowledged.

The claims in the application are claims 1,2,4,6-17.

After further review and consideration, this application is found in condition for allowance for the reasons stated bellow.

#### 1. *Specification*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicants were advised to change the title in Office Action paper # 2 dated 2/26/02, but the same has not been done.

#### 2. *Claim Rejections - 35 U.S.C. § 112*

Rejections made under 35 U.S.C., second paragraph for claims 1,4,6,12 are **maintained** further for reasons already stated in earlier Office Action paper # 4 dated 8/7/02, and following additional reasons

The Proviso statement in claims 1 and 2 are unclear, see: "when n represents 0 and B is 4-methylpiperidiny1, B is not bromo phenyl, chlorophenyl ....".

Therefore, B is not 4-methyl piperidiny1 in the claim(s) 2. It is very confusing to read the claims for the excluded data.

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**3.** ***Claim Rejections - 35 U.S.C. § 102***

Rejections made under 35 U.S.C. 102 (b) ( e.g. Cho et al and others) for claims 1,2,4,7 are not overcome by the amendment. New claim 17 is also rejected under 35 U.S.C. 102 (b) for the reasons stated in earlier paper and additional below mentioned reason(s). Therefore, the same has been **maintained** further.

Applicants rely on disclaimer (or proviso) to overcome the rejections. However, the reference teaches 4-methyl-piperazinyl and the proviso excludes 4-methyl piperidinyl compounds. Therefore, the “proviso” is not sufficient to overcome the rejections.

**3.1. New Rejections:**

Claims 1,2,4,6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Aebi, Albert et al ( CH 438308; also cited as Chem. Abstract: 69:35972-1968:435972). In the instant claims, the compounds similar to ref.' 108 are arrived at by computing various values for the variable(s) B as: “ when B is “ an optionally N-substituted amino lower alkyl” which includes -CH<sub>2</sub>-N of piperidine and other compounds( see Example 2 in columns 5-6 and also Examples 3-4 in column 6, and Example 7 in columns 7-8 respectively) having CAS RN # 14657-46-6 = Isoquinoline, 4-methyl-1-(1-piperidinyl)3-(1-piperidinylmethyl)-.

**4.** ***Claim Rejections - 35 U.S.C. § 103***

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Rejections made under 35 U.S. 103(a) ( e.g. Simmonds et al ) for claims 1,2,4,7 are not overcome by the amendment. Therefore, the same have been maintained further.

**4.1. New Rejections:**

Claims 1,2,4,6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Behrens, Carl H.(Chemical Abstract. 113:211863; also cited as U.S.P.4942163).

The reference '163 teaches the making of substituted isoquinolinones and 1-Isoquinolineamine derivatives and their activity as chemotherapeutic agents. See for 3-naphthyl derivative Table 1 in column 12; Table 2 in columns 14,15 wherein X = 4-alkyl substituted piperazines in Examples 25-33).

The instant claims differ by having the substituents at different positions than the reference compounds e.g. in the claims B can be phenyl/aryl and R3 can be Me.

Applicants' "proviso" excludes 1-naphthyl derivatives but one skilled in the art would be motivated to make structural isomers , 2-naphthyl derivatives.

While applicants claim novel compounds having pharmaceutical use, their attention is drawn to the fact that compounds having the same radicals at different positions on the nucleus are position isomers. Position isomerism involves close structural similarity and are expected to possess similar chemical and physical properties. Thus, the disclosure of the compound itself renders prima facie obvious over its isomers. Isomer is expected to be preparable by the same method and to have the same properties. This expectation is then deemed the motivation for preparing isomers and isomeric compounds as claimed herein. The claimed compounds are

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isomer(s) of the reference compound and are unpatentable over the prior art unless the same possess some unobvious or unexpected beneficial property not possessed by the prior art. In re Jones (CCPA 1947) 102 F2d 638, 74 USPQ 152. In re Norris (CCPA 1950) 179 F2d 970, 84 USPQ 458.

One of ordinary skill in the art would have been motivated to make the claimed compounds by exchanging the position(s) of the naphthyl from 1-position to 2-position or other(s) groups of the ref. '163 since such compounds would have been suggested by the reference as a whole. The requisite motivation stems from the expectation that compounds so structurally similar would be expected to possess pharmaceutical properties (in re Wood, 199 USPQ 137). Thus, it would have been obvious to make 2-naphthyl compounds with isoquinoline core and expect similar pharmaceutical activity as claimed herein.

## 5.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel whose telephone number is (703) 308 4709.

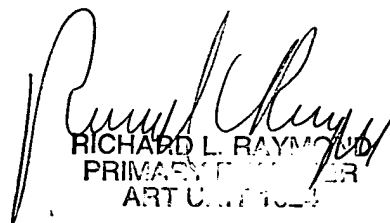
The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Patent Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.



Sp/ January 16, 2003.



RICHARD L. RAYMOND  
PRIMARY EXAMINER  
ART UNIT 1624